FDA 510(k) Premarket Notification

K931743 BURRON CARDIOVASCULAR ANGESTAT(TM)

CLEARED

Nov 2, 1993
209 days to decision

K931743 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k931743/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 7, 1993
Decision date	Nov 2, 1993
Days to decision	209 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**B.Braun Medical, Inc.**
Location	Plymouth, MN, US
Contact	STEVE HUNTLEY
Website	http://www.bbraunusa.com/
510(k) history	149 submissions · 146 cleared · 1993-2026

B.Braun Medical, Inc. is a leading medical technology company specializing in infusion therapy, vascular access, and hospital-based medical devices. The company operates with a manufacturing facility in Plymouth, Massachusetts. B.Braun Medical has maintained a strong FDA 510(k) regulatory record since 1993. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2025 demonstrate continued innovation in infusion pumps, IV catheters, and administration sets for general hospital use. The company's cleared device portfolio focuses on smart ...